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### REMARKS

Claims 1-51 were subject to examination in the Final Action dated September 9, 2003. Claims 1, 7, 15, 22, 30 and 48 have been amended by the amendment presented above. Claim 40 has been canceled, and new Claims 52 and 53 have been added. The specification has been amended at page 5, lines 14-25, to re-enter the language "sodium chloride."

Applicants note with appreciation that the only remaining rejections in this application are under §112, second paragraph. These rejections as well as other outstanding issues are discussed below.

#### I. Claim Amendments.

Claims 1, 30 and 48 have been amended to remove the Markush language. Claim 1 has further been amended to add a an "or" to clarify the listed salts.

Claim 7 has been amended to independent form and to provide better antecedent basis in the last line without altering the scope of the claimed subject matter.

Claim 15 has been amended to recite "in an amount sufficient to eliminate undesirable non-protozoan microbiological growth." This claim language is clear from the teachings of the specification. For example, at page 8, lines 3-4, the specification states: "the oxidant is added in a sufficient amount to inactivate the undesirable microbial growth in the aqueous suspension." It would be implicit to one of ordinary skill reading the specification that "undesirable" microbial growth excludes the protozoan oocysts, as the purpose of the claimed method is to sporulate the protozoan oocysts, and not to inactivate or eliminate them.

Claim 22 has been amended to recite "adding a bleaching agent to the sporulated or sporulating oocysts" to clarify the claim language. To illustrate, Claim 23 recites that sporulation and bleaching can occur concurrently. According to this embodiment, the oocysts would not be "sporulated" already when the bleaching agent is added. Claim 22 as originally presented

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encompassed both sequential and concurrent sporulation/bleaching steps, which scope is clearer from the amended claim language.

Finally, dependent Claims 52 and 53 are newly-added. Claim 52 recites "wherein the hydrogen peroxide is initially present in an amount from about 2,000 to about 20,000 mg/l" and is supported by the specification at page 8 (lines 28-30). Claim 53 is similar to Claims 19, 22, 29, 39 and 43 and recites different species of *Eimeria*. These claims are added to provide a more complete claim set. Further, applicants submit that these amendments do not raise new substantive issues.

## II. Telephone Interview.

Applicants wish to express their appreciation for the Examiner's time and courtesy during the telephone interview conducted with Applicants' representative, Karen Magri, on November 20, 2004. During the course of the telephone interview, clarification of some of the rejections was requested. In addition, possible claim language was discussed. Finally, the propriety of the finality of the present office action was briefly raised. The Examiner indicated that he would consider this issue once a written response is submitted outlining the basis for Applicants' assertion that the finality of this office action is premature is submitted.

## III. The Finality of the Office Action is Premature.

Applicants submit that the finality of the present Office Action is improper, and request that, if a Notice of Allowance is not issued following consideration of this Amendment, the Examiner withdraw the final rejection. The Action states, at page 5, that "Applicant's amendment necessitate the new ground(s) of rejection presented in this Office Action. Accordingly, this action is made final." Applicants respectfully disagree as at least two of the new grounds of rejection were not necessitated by Applicants' previous amendment and, further, that these grounds of rejection could have been made in the first Office Action.

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The M.P.E.P. § 706.07(a) states that:

Under present practice, second or any subsequent actions on the merits shall be final, except where the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p).

In the instant case, the new rejection of Claims 7-14 (in Point 15) and the rejection of Claim 40 (in Point 17) were not necessitated by Applicants' amendments and could have been presented earlier. With respect to Claim 7, the language the Examiner finds objectionable was present in the claim as originally filed. This language was not amended at all in Applicants' first amendment dated June 18, 2003.

With respect to new Claim 40, this claim is a rewriting of original Claim 1. Original Claim 1 recited (emphasis added):

A method for the purification and recovery of encysted protozoa, comprising separating the encysted protozoa from a suspension comprising the encysted protozoa by a salt flotation process wherein the salt comprises sulfates, phosphates, nitrates, acetates of ammonium, sodium, potassium, calcium, magnesium, or zinc, hydrogen-bonded organics, the salts of guanidiene, or mixtures thereof, or a gas flotation process.

The underlined language was omitted from Claim 1 and presented in a new Claim 40 so that the salt flotation and gas flotation embodiments of the invention would be presented in separate independent claims. The outstanding rejection regarding Claim 40 could have been made against original Claim 1 in the first Office Action and was not necessitated by adding a new independent Claim 40.

In view of the foregoing, in the event that a Notice of Allowance is not issued after consideration of this response, it is requested that the finality of the present Action be withdrawn.

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**IV. Rejections under 35 U.S.C. § 112, second paragraph.**

The claims stand rejected on various grounds of indefiniteness under §112, paragraph 2. The individual rejections are addressed below.

**A. "Unwanted microbial growth."**

The rejection against Claims 15-17 on the basis that the term "wherein the hydrogen peroxide is present in an amount sufficient to eliminate unwanted microbial growth" is maintained. The Applicants previously argued that the term is intended to indicate that the level of microorganisms other than the oocysts is reduced or eliminated. The Examiner did not find this argument persuasive and stated that "[i]t is recommended that the applicants amend the claims to reflect what they 'intend'." Applicants have amended the claims to recite "an amount effective to eliminate undesirable non-protozoan microbial growth." Those of ordinary skill in the art would recognize that the sporulation conditions (e.g., time and concentration of hydrogen peroxide) can be altered to vary the amount of microbial inactivation achieved. In some embodiments of the invention, it is desirable that the sporulation step results in sterilization of the suspension (*i.e.*, any microbial growth other than the oocysts is undesirable), for example, to produce an *in ovo* avian vaccine. In other embodiments, however, it may not be necessary to completely eliminate the microbial load and some residual microbial growth other than the oocysts is acceptable (*i.e.*, less than 100% elimination is acceptable). For example, the process may contain a later sterilization procedure or it may not be necessary to produce a sterile product (for example, to produce a post-hatch avian vaccine or a mammalian vaccine).

In view of the foregoing, Applicants submit that the language of Claim 15 (and dependents) satisfies the requirements of §112, second paragraph, and respectfully request that the rejection on this basis be withdrawn.

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**B. Objection to Amendment to the Specification.**

The Action raises an objection to the previous amendment to the specification to delete the term "sodium chloride" on the basis that it introduces new matter. Applicants disagree with this objection, but have nonetheless reintroduced the deleted language into the specification in the amendment presented herein. The previous amendment has no effect on the claim scope; Applicants merely submitted this amendment in the belief that it is in the public's interest to have the patent publish with the correct information. The inclusion of "sodium chloride" as one of the salts is an obvious error that would be apparent to one of ordinary skill in the art in view of the specification as a whole. To advance the prosecution of this application to allowance, Applicants have presented an amendment herein to reincorporate the deleted language back into the specification.

**C. "Salt Selected from the Group Consisting of."**

Claims 1 and 30 stand rejected for reciting "a salt selecting from the group consisting of." The Action states that the meaning of this claim language is unclear as the term "comprises" is open-ended language, whereas "selected from the group consisting of" is generally considered close-ended language. As discussed with the Examiner during the telephonic interview, it is intended that the salt include (i.e., comprise) at least one of the listed salts or a mixture thereof. The "comprises" language indicates that the salt can also contain other salts.

Applicants have omitted the Markush group language from Claims 1, 30 and 48 to clarify this point. Applicants note for the record that this is not a narrowing amendment.

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**D & E. "At Least One Flotation Cell."**

Claims 7-14, 18-27 and 41-51 stand rejected for indefiniteness on the basis that it is unclear which is "the" cell from which the oocysts are recovered when multiple cells are involved. The last two lines of Claim 7 now recite:

"passing the conditioned suspension through at least one gas flotation cell; and

recovering the encysted protozoa from the at least one gas flotation cell."

Thus, the gas flotation process of Claim 7 recites passing the conditioned suspension through one or more gas flotation cells. Typically, when multiple cells are involved, the oocyst fraction will be collected from one cell and then passed into the next cell until the last cell is reached. The oocyst fraction is then "recovered" from the last cell. However, Applicants note that it is not necessary that the oocysts be collected from the last cell. The invention could be practiced to recover oocysts from each cell in the series and the recovered oocysts pooled.

In view of the foregoing comments, Applicants submit that the claimed subject matter of Claim 7 is sufficiently clear, and respectfully request that the rejection on this basis be withdrawn.

**F. Essential Steps of Gas Flotation Process.**

Claim 40 stands rejected for omitting essential steps in the gas flotation process. Applicants respectfully disagree as any suitable gas flotation technique can be employed with the present invention. Nonetheless, to expedite the prosecution of this application to allowance, Applicants have canceled Claim 40 and put Claim 7 to independent form.

**V. Conclusion.**

The concerns of the Examiner having been addressed in full, Applicants respectfully request withdrawal of all outstanding rejections and the

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Issuance of a Notice of Allowance forthwith. The Examiner is encouraged to address any questions regarding the foregoing to the undersigned, who may be reached at (919) 854-1400.

Respectfully submitted,

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